

TSCA Interagency Testing Committee Actions Related to Phthalates

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The Interagency Testing Committee was established by the Toxic Substances Control Act in October 1976 and has the statutory responsibility to identify and recommend to the EPA Administrator chemical substances or mixtures that should be given high priority for testing to determine the hazard to human health and to the environment. Under TSCA, testing is the responsibility of industry.

The TSCA Interagency Testing Committee had 6 months (April 1977 to October 1977) to compile the Preliminary List. This list of approximately 300 substances, mixture or categories was published in July 1977. On this list appeared the alkyl phthalates (short- and long-chain). Comments were requested on the procedures used to develop the list and on specific items on the list (1). At that time the TSCA Chemical Substance Inventory was not ready. Chemicals on the initial list were then screened for their potential for adverse effects in humans and in the environment. A dossier was prepared on alkyl phthalates by the supporting contractor and information on the phthalates listed in Table 1 was presented.

After detailed review by the Committee, the category was recommended for environmental effects testing in the Initial Report dated October 12, 1977. The category was defined by the Committee as all alkyl esters of 1,2-benzenedicarboxylic acid produced in quantities of 10 million lb/yr or greater. The potential for exposure due to phthalates reaching the aquatic environment, persistence and accumulation in aquatic organisms were major causes for concern. Some phthalates are produced in

Table 1. Alkyl phthalates.

Short chain	Long chain
Dibutyl phthalate	Di(2-ethylhexyl) phthalate
Diethyl phthalate	Dicyclohexyl phthalate
Dimethyl phthalate	Diisodecyl phthalate
	Diisooctyl phthalate
	Dioctyl phthalate
	Ditridecyl phthalate
	N-Octyl n-decyl phthalate

volumes over 100 million lb/yr and are widely used as plasticizers in a variety of products.

As a result of the second scoring exercise (1979), benzyl butyl phthalate (BBP) and butyl glycolyl butyl phthalate (BGBP) were selected for further study. Hazard Information Reviews were prepared by the support contractor. After Committee review both were recommended for testing in the Seventh Report to the EPA Administration in October 1980. Butyl glycolyl butyl phthalate was recommended because of its high exposure potential and inconclusive findings suggesting leukemia in a long-term rat study and in another study, results suggesting reproductive effects. In the case of butyl glycolyl butyl phthalate (BGBP), mutagenic and short-term genotoxic testing was recommended because of inconclusive test results. Existing data on BGBP and other phthalates indicate the need to determine the compound's potential reproductive effects. Both BBP and BGBP were recommended for environmental effects testing because little information is available on this effect. Structurally, similar phthalate esters are toxic to aquatic organisms in parts per billion ranges and have the potential to bioaccumulate.

In the third scoring exercise (1980), dimethyl phthalate and butyl 2-ethylhexyl phthalate were selected for further evaluation (2). Recent informa-

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Table 2. ITC recommendations on phthalates.

Category or chemical	Recommended studies	Date of recommendation
Alkyl phthalates	Environmental effects	Initial Report Oct. 12, 1977 (3)
Benzyl butyl phthalate	Carcinogenicity Reproductive effects Environmental effects	Seventh Report Nov. 25, 1980 (4)
Butyl glycolyl butyl phthalate	Mutagenicity and other short-term tests for genotoxic effects Reproductive effects Environmental effects	Seventh Report Nov. 25, 1980 (4)

tion generated by various groups suggests that health effects of this group may be of concern. However, the Committee has deferred any further recommendation related to health effects testing for individual phthalates or category until after this

Conference. The Committee will take into account all the information presented at this meeting.

The TSCA ITC recommendations on phthalates are summarized in Table 2.

REFERENCES

1. Preliminary List of Chemical Substances for Further Evaluation. Toxic Substances Control Act Interagency Testing Committee, July 1977.
2. Toxic Substances Control Act Interagency Testing Committee, Chemicals to be Reviewed by the TSCA ITC, Notice of Public Meeting. Fed. Reg. 45 (No. 196): 66506-66513 (Oct. 7, 1980).
3. Initial Report to the Administrator, EPA, TSCA Interagency Testing Committee, Fed. Reg., 42 (No. 197): 55026-55080 (Oct. 12, 1977); corrections, 42: 58777-58778 (Nov. 11, 1977). Supporting dossier published by EPA, January 1978, EPA 560-10-78/001.
4. Seventh Report of the TSCA Interagency Testing Committee to the Administrator, EPA, Fed. Reg., 45 (No. 229): 78432-78446 (Nov. 25, 1980).